Guidance for Industry and FDA Staff

"Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act

DRAFT GUIDANCE

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For questions regarding this draft document contact Carol Drew at 877-287-1373.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

June 2010

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Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850
Phone: 1-877-287-1373
http://www.fda.gov/tobaccoguidance

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products (CTP)
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Contains Nonbinding Recommendations

Draft — Not for Implementation

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Guidance for Industry and FDA Staff[1]

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I. INTRODUCTION

Section 904(e) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) (21 U.S.C. 387d(e)), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) requires FDA to establish a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand (the HPHC list). This guidance document discusses the meaning of "harmful and potentially harmful constituent" in the context of implementing the HPHC list requirement.

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II. BACKGROUND

On June 22, 2009, the President signed the Tobacco Control Act into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 904(e) to the FDCA, requiring FDA to establish, and periodically revise, a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand.

[1] This guidance has been prepared by the Office of Regulations in the Center for Tobacco Products (CTP) at FDA.

III. DISCUSSION

For the purpose of establishing "a list of harmful and potentially harmful constituents, including smoke constituents, to health in each tobacco product by brand and by quantity in each brand and subbrand," as required under section 904(e) of the Act, FDA believes that the phrase "harmful and potentially harmful constituent" includes any chemical or chemical compound in a tobacco product or in tobacco smoke:

a) that is or potentially is inhaled, ingested, or absorbed into the body; and

b) that causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products. Examples of constituents that have the "potential to cause direct harm" to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds. Examples of constituents that have the "potential to cause indirect harm" to users or non-users of tobacco products include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by: 1) potentially facilitating initiation of the use of tobacco products; 2) potentially impeding cessation of the use of tobacco products; or 3) potentially increasing the intensity of tobacco product use (e.g., frequency of use, amount consumed, depth of inhalation). Another example of a constituent that has the "potential to cause indirect harm" is a constituent that may enhance the harmful effects of a tobacco product constituent.